ARIC Manuscript Proposal #3562

| PC Reviewed: 2/11/20 | Status: | Priority: 2 |
|----------------------|---------|-------------|
| SC Reviewed: | Status: | Priority: |

1.a. Full Title: Relationship between Mid-Upper Arm Circumference and Body Mass Index in ARIC participants.

b. Abbreviated Title (Length 26 characters): Arm Circumference and BMI

2. Writing Group:

Writing group members: Carin Northuis, Thomas Murray, Pam Lutsey, Steven Nguyen, Priya Palta, Ken Butler, Kamakshi Lakshminarayan, others welcome

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. CN [please confirm with your initials electronically or in writing]

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ARIC author to be contacted if there are questions about the manuscript and the first author does not respond or cannot be located (this must be an ARIC investigator).

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3. Timeline: Data analyses to begin immediately after proposal approval; A manuscript is expected to be prepared within 6 months.

4. Rationale:

Electronic health records (EHR) are frequently used for patient screening and recruitment in clinical trials.¹⁻² However, EHR may not contain all relevant screening data. Surrogate variables

within the EHR can be used to improve the efficiency of patient screening. A surrogate variable can be an effective substitute if it can predict the actual variable of interest with accuracy.

Herein, we propose the development of a prediction rule linking a variable readily found in the EHR, body mass index (BMI), to arm circumference. This prediction rule is proposed to facilitate the recruitment for an ongoing NIH trial of blood pressure home monitoring in patients with uncontrolled hypertension (mGlide, R01 HL138332).

Blood pressure (BP) monitors have multiple cuff sizes to accommodate the range in patient arm circumference. Monitors have a cut off value for arm circumference beyond which the measured BP is not considered reliable even with the largest available cuff. For our trial of self-monitoring, we wanted to use the EHR to screen for patients who would be eligible for a trial self-monitoring and exclude those whose arm circumference was too large for accurate home monitoring of BP. Arm circumference is rarely recorded in the EHR of adult patients. However, BMI is a promising surrogate variable for arm circumference and is almost always recorded in the EHR.

There are few papers reporting on the relationship between arm circumference and BMI.³⁻⁴ These are typically in the context of malnutrition rather than in a normal general population, and most focus on youth rather than adults. These studies report a high correlation between BMI and arm circumference (r=0.74-0.86).³⁻⁴ The ARIC data set provides an opportunity to contribute to the literature linking BMI and arm circumference in a bi-racial population-based cohort of adults. Findings (which may ultimately take the form of a brief report) would have practical implications for studies involving blood pressure self-monitoring.

In this manuscript, we will analyze the relationship between BMI and arm circumference using data in ARIC Visit 4. Analyses will examine sensitivity and specificity of using various diagnostic BMI cut points for predicting arm circumference outcomes. The American Heart Association recommends the following bladder ranges for blood pressure cuffs: 22 cm (small adult), 30 cm (adult), 36 cm (large adult), 42 cm (extra-large adult).⁵ The typical arm circumference for each category ranges from 22-26 cm for small adult, 27-34 cm for adult, 35-44 cm for large adult, and 45-52 cm for extra-large adult.⁵ Since bladder and cuff sizes may vary by manufacturer, we selected arm circumference cuts of ≤ 26 cm vs ≥ 26 cm, ≤ 34 cm vs ≥ 34 cm, ≤ 42 cm vs ≥ 44 cm since these are the ranges specified by BP monitor cuffs widely available in the market. Specifically, the mGlide trial is utilizing a blood pressure cuff with a bladder of 42 cm and therefore has been incorporated into the cut points. We also propose identifying BMI cut points by sex, race, and age group (<60 years and ≥ 60 years). We will determine whether the overall BMI cut point for each measure of arm circumference is independent of age, sex, and race.

5. Main Hypothesis/Study Questions:

• BMI and arm circumference are highly correlated with each other and BMI can be used to predict arm circumference with high sensitivity and specificity.

6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).

Study Design: Cross-sectional analysis

Inclusion: Participants who are of black and white race, attended visit 4, and have complete anthropometric (e.g., BMI and arm circumference) and demographic (sex, race, age) data. **Outcome:** Arm circumference taken at visit 4, dichotomized at ≤ 26 cm vs greater than 26 cm; ≤ 34 cm vs greater than 34 cm; ≤ 42 cm vs greater than 42 cm; and, ≤ 44 cm vs greater than 44 cm. **Independent Variable:** BMI measured at visit 4 **Other Covariates:** Sex, Age, Race (all measured at visit 4)

Data Analysis:

Pearson's correlations will be reported. We will also develop receiver operating characteristic (ROC) curves to measure the sensitivity and specificity of the diagnostic (BMI<x) for predicting outcome (arm circumference values). This will provide the BMI threshold (x) with the best sensitivity and specificity profile for a specific arm circumference range (e.g. arm circumference \leq 42 cm vs greater than 42cm). We will use the probability threshold that maximizes Youden's index. Generalized linear models will evaluate if the various BMI cut points differ by age, sex, and race.

7.a. Will the data be used for non-ARIC analysis or by a for-profit organization in this manuscript? ____ Yes \underline{X} No

b. If Yes, is the author aware that the current derived consent file ICTDER05 must be used to exclude persons with a value RES_OTH and/or RES_DNA = "ARIC only" and/or "Not for Profit"? ____ Yes ____ No (The file ICTDER has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript? _____ Yes X No

- 8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the current derived consent file ICTDER05 must be used to exclude those with value RES_DNA = "No use/storage DNA"? ____ Yes ____ No
- 9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: <u>http://www.cscc.unc.edu/aric/mantrack/maintain/search/dtSearch.html</u>

X Yes _____ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

The following publication from 1995 is related but does not address the topic of our proposal and there is no analytic overlap: Duncan BB, Chambless LE, Schmidt MI, Szklo M, Folsom AR, Carpenter MA, Crouse JR III, The Atherosclerosis Risk in Communities (ARIC) Study Investigators. Correlates of body fat distribution: Variation across categories of race, sex, and body mass in the atherosclerosis risk in communities study. Annals of Epidemiology. 1995;5:192-200

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? ____ Yes X No

11.b. If yes, is the proposal

| | A. primarily the result of an ancillary study (list number*) | |
|--------|--|----|
| | B. primarily based on ARIC data with ancillary data playing a minor ro | le |
| (usual | lly control variables; list number(s)* | _) |

*ancillary studies are listed by number https://sites.cscc.unc.edu/aric/approved-ancillary-studies

12a. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.

12b. The NIH instituted a Public Access Policy in April, 2008 which ensures that the public has access to the published results of NIH funded research. It is **your responsibility to upload manuscripts to PubMed Central** whenever the journal does not and be in compliance with this policy. Four files about the public access policy from http://publicaccess.nih.gov/ are posted in http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to PubMed central.

References

- 1. Kopcke F, Trinczek B, Majeed RW, Schreiweis B, Wenk J, Leusch T, Ganslandt T, Ohmann C, Berge B, Rohrig R, Dugas M, Prokosch HU. Evaluation of data completeness in the electronic health record for the purpose of patient recruitment into clinical trials: a retrospective analysis of element presence. BMC Med Inform Decis Mak. 2013;13:37.
- Bruland P, McGilchrist M, Zapletal E, Acosta D, Proeve J, Askin S, Ganslandt T, Doods J, Dugas M. Common data elements for secondary use of electronic health record data for clinical trial execution and serious adverse event reporting. BMC Med Res Methodol. 2016;16:159.
- 3. Brito NB, Llanos JPS, Ferrer MF, Garcia JGO, Brido ID, Castro FPG, Castellanos NC, Rodriguez CXA, Abizanda EP. Relationship between mid-upper arm circumference and body mass index in inpatients. PLOS ONE. 2016;11:e0160480.

- 4. Kumar P, Sinha R, Patil N, Kumar V. Relationship between mid-upper arm circumference and BMI for identifying maternal wasting and severe wasting: a cross-sectional assessment. Public Health Nutr. 2019;22:2548-2552.
- 5. Muntner P, Shimbo D, Carey RM, Charleston JB, Gaillard T, *et al.* Measurement of blood pressure in humans: A scientific statement from the American Heart Association. Hypertension. 2019;73:e35-e66.